AN IMPERIAL PHARMACOPEIA.

A REVIEW OF THE REPORT SUBMITTED TO PARLIAMENT BY THE SUB-COMMITTEE OF THE COMMITTEE OF CIVIL RESEARCH, ON THE BRITISH PHARMACOPEIA.

BY QUARTERMASTER SERJEANT E. F. SMITH, M.M.

ROYAL ARMY MEDICAL CORPS.

There have been plenty of critics of the British Pharmacopoeia since its inception, but the last edition of 1914, appearing as it did in stirring times, did not receive the same attention and abuse as did its predecessors. Nevertheless it has now been judged and found wanting. The Committee of Civil Research at a meeting held on July 29, 1926, appointed a sub-committee:

"To make inquiries, to collect information, to receive evidence, and to make recommendations on the question whether it is desirable to make any, and if so what alterations in the existing law of practice relating to the preparation or publication of the British Pharmacopoeia and to its adaptation to the requirements of the British Empire."

This sub-committee which has just issued its report was composed as follows:

Sir Donald MacAlister, Bt., K.C.B.
Dr. H. H. Dale, C.B.E., F.R.S.
Mr. Edmund White, B.Sc., F.I.C.
Dr. H. G. Dain.
Mr. A. F. Hemming, C.B.E.

The report is exceedingly interesting and concise, revealing the conscientious and painstaking labours of the committee which was entirely unbiased from the commencement, and which patiently examined the claims put forward by numerous authorities for the betterment of the "mother of pharmacopoeias."

On December 3, 1926, the committee commenced hearing the statements of the joint editors of the B.P. of 1914. They then inquired into the financial arrangements adopted by the Registrar of the General Medical Council with regard to the preparation of the British Pharmacopoeia, and proceeded to examine representatives of the Ministry of Health, and those of various learned bodies and societies which were interested parties.

At a later stage evidence was considered from the Chairman of the Committee of Revision of the Pharmacopoeia of the United States, and finally, the committee went into the criticisms levelled by certain of the Dominions,
through their representatives. It would appear to be a matter for regret that no evidence was obtained from the Army and Navy authorities, who after all have an interest in the subject.

In addition to oral evidence the committee "received a large number of written communications" from various sources which they thoroughly examined. These communications included letters and telegrams from certain of the Dominion Governments. Copies of the following official pharmacopoeias were purchased in order that the methods of other countries might be studied with a view to improving the B.P.: U.S.A., Germany, France, Holland, Sweden, Italy, Austria, Belgium, Norway and Switzerland.

The report contains an official survey of the British Pharmacopoeia: (a) Before the Medical Acts, and (b) after the Medical Acts. Some of these points were touched upon in the writer's previous article.1

It is interesting to note that prior to the Medical Act of 1858, the Irish Parliament in 1760, the only one of the three kingdoms to do so, "gave statutory effect to a Pharmacopoeia." This act "empowered the College to appoint four of its members to be inspectors of the laboratories and shops of apothecaries, chemists and druggists in Dublin and within a ten miles radius, and the Master and Warden of the Apothecaries were directed to elect two assistants to the inspectors. The Act directed that all drugs found to be unsound, corrupt, adulterated or unfaithfully, dishonestly or unskilfully compounded or otherwise so prepared as to be rendered unwholesome or unfit to be used as medicine for the health of man's body should be burned or destroyed by the College beadle."

The authors of the B.P. of 1914 made an honest attempt to bring the work into line with the demands of the Dominions, and with this end in view Professor Norman Collie, and Professor Greenish, Dean of the School of Pharmacy, undertook important researches. The Pharmacopoeial Committee of the General Medical Council "improved by the starting of a reference collection of medical plants and other articles of materia medica, and a reference library of pharmacopoeial literature was also inaugurated to which many interesting donations were made."

An International Pharmacopoeial Conference was held at Brussels in 1902, with the object of attempting to standardize the composition and strength of certain potent drugs universally employed. A representative of the British Government attended with a nominee of the Government of India. This conference recommended the institution of a permanent Secretariat at Brussels, and was generally in agreement as to the strengths to be adopted.

Finally, all the delegates undertook to recommend to their respective Governments the adoption of the international standards agreed upon in

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the next revision of their pharmacopoeias. The British Government expressed its agreement subject to the reservation of the right "of introducing into the stipulations of the present agreement such modifications in details as the progress of medical and pharmaceutical science may render necessary." As a matter of fact when the 1914 edition of the B.P. appeared there were very few changes necessary to comply with these recommendations.

There is not space to describe the continuous and painstaking work which after 1909 led up to the 1914 edition. It will be sufficient to refer to one instance of the labours performed by the Committee of Reference in Pharmacy, which submitted in 1908 "a report on the frequency or infrequency with which medicines, official or non-official, were prescribed in the United Kingdom, based on an analysis of 48,000 prescriptions."

In 1914 the fifth and current B.P. was completed and was about to be issued when war broke out, and publication had to be postponed until December 31, 1914. Professors Tirard and Greenish were the editors. No two men could have been more fitted for the work. Professor Greenish has always insisted on the facilities which exist, but alas so often neglected, for the growth of medicinal plants within the Empire which probably has the monopoly of their consumption.

The following table gives the number of copies of the B.P. sold since its first inception, and shows a steady increase:

<table>
<thead>
<tr>
<th>Edition</th>
<th>Year</th>
<th>Copies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>1964</td>
<td>13,000</td>
</tr>
<tr>
<td>2nd</td>
<td>1867</td>
<td>37,606</td>
</tr>
<tr>
<td>3rd</td>
<td>1885</td>
<td>44,528</td>
</tr>
<tr>
<td>4th</td>
<td>1908</td>
<td>46,081</td>
</tr>
<tr>
<td>5th</td>
<td>1914</td>
<td>52,756</td>
</tr>
</tbody>
</table>

Addendum, 1874, 11,040
Addendum, 1890, 14,732
Addendum, 1901, 4,525
(To November 30, 1926)

VACCINES AND SERA.

Whilst the 1914 edition was in course of preparation, the question was raised as to the advisability of including therapeutic sera and vaccines, which were becoming so important a factor in the modern treatment of disease, and which could not be put to the ordinary chemical tests as to their purity and potency. After consideration the suggestion was ruled out as impracticable until such time as the institution of a national centre, which would be empowered to carry out such biological and physiological tests as would ensure a necessary standard. The U.S.A. pharmacopoeia of 1916 included these items, but had the necessary backing in the recommendations of eminent scientists employed in a national institution for this purpose.

In 1920 the Ministry of Health set up a committee "to advise on the measures to be taken for the effective control of the therapeutic substances in question" and in 1925, as a result of their deliberations the Therapeutic Substances Act became law. Section 5 of this act legislates for the making of regulations to prescribe *inter alia* (a) The standard of strength, quality of the vaccines and sera; (b) The tests to be made; and (c) Units
of standardization to be adopted. These regulations were to be drawn up by a Joint Committee composed of the Minister of Health, The Secretary of State for Scotland, and the Minister of Home Affairs for Northern Ireland, or by deputies appointed by these officials, after consultation with an advisory committee of eight members to be appointed by the aforesaid officials, and the Councils of the various important medical and pharmaceutical bodies of Great Britain.

Since 1921, work has been going on continuously towards the revision of the B.P.

The second International Conference on the Unification of the Formule of Powerful Medicaments was held at Brussels in 1925, at which this country was again represented. The second conference advised "the recognition of biological methods of standardization, which have been, or may be, recommended by the Health Section of the League of Nations," and approved of the formation of an international secretariat for the unification of Pharmacopoeias, while recognizing that the conditions of its establishment must be determined by the League of Nations. Similar reservations were applied to the proposed formation of two other international committees for the investigation of assay processes and methods of making galenical preparations. The British delegates, while in general agreement with the conclusions of the Conference, notified certain reservations.

In 1921, the Pharmacopoeia Committee of the General Medical Council received an offer to co-operate in "matters of common pharmaceutical interest" from the United States authorities, and this offer was gratefully accepted.

In 1925, the Committee were able to recommend that the necessary steps should be taken towards the issue of a new edition of the B.P. Dr. Philip Hamill, lecturer on Pharmacy and Therapeutics at St. Bartholomew's Hospital, was appointed as secretary to assist in the work, and as a result of inquiries and representations, it was thought advisable to convene a conference on February 23, 1926, to which invitations were issued to the various medical, pharmaceutical, and scientific bodies of the kingdom. It was as the direct result of this conference that the Inquiry under review was set up.

The Report has an interesting section on the inquiry which was made into the present legal status of the B.P. The Medical Act of 1862, besides vesting in the General Medical Council the sole right of printing and selling the B.P., went on to state that "any person . . . who shall compound any medicines of the British Pharmacopoeia except according to the formularies of the said Pharmacopoeia shall for every offence be liable to pay a penalty or sum of Five Pounds." Subsequent Acts made similar regulations, and in 1924 the National Health Insurance Act in laying down a Drug Tariff containing 679 drugs and preparations to be supplied to
insured persons, insisted on the standards laid down in the B.P. unless otherwise stated. Naturally these acts were open to a good deal of criticism, for it stands to reason that if any drug referred to in the B.P. was asked for, and that drug did not comply with the tests and standards laid down therein, then the person who supplied it would be guilty of an offence.

To quote from the Report: “But the standards of the B.P. are not absolute standards. It is admissible to prove in defence that there is some other commercially recognized standard for the article with which the article supplied complied. There are various articles in the B.P. which are used not only medicinally, but also for domestic purposes, and a standard appropriate for the article when intended for medicinal use may be quite inappropriate for it when intended for household use. Thus ‘sherry’ finds a place in the B.P., but the housewife who purchases what is euphemistically known as cooking sherry from her grocer is certainly not thinking of the British Pharmacopoeia. . . . Where directions only are given for compounding a particular medicament, it does not follow that the medicament when compounded will contain the prescribed ingredients in the same proportions, for internal changes may result from the compounding of them.”

**MAIN CRITICISMS SUMMARIZED.**

The chief criticisms worthy of consideration which the Committee, after hearing evidence, regarded as important can be summarized as follows:

1. The effect of the Medical Acts of 1858 and 1862, was to cause to be published under their direction a B.P., but how they were to carry out this injunction was left entirely to their discretion.

2. Dissatisfaction regarding the methods adopted by the General Medical Council in carrying out the instructions laid upon them. It would appear that ever since the early editions of the B.P. were published, criticism has been directed against the fact that specialists in pharmacy are not sufficiently consulted, whilst too many physicians and surgeons, who had no really first hand knowledge of pharmaceutical processes, were given the work of directing the compilation of the volume. The same criticism crops up again as regards the current edition. It must be remembered that the General Medical Council is responsible for the issue of the B.P., and it has been represented that if the work of the distinguished pharmacists who were consulted was essential towards efficiency, why should they not be recognized as participants rather than consultants?

3. That the technical work performed by pharmaceutical experts was afterwards submitted to a committee, which was not fully competent to criticize it or accept it, but which, nevertheless, had the power to alter or modify it.

4. That the Pharmacopoeia Committee of the General Medical Council is not a permanent organization, and that after the bringing out of a new B.P., no continuous work was carried on with a view to future issues—
although, as we have seen, much valuable work has been carried out since
the Edition of 1914.

(5) The omission of certain sera and vaccines and other remedies of
animal and bacteriological origin.

(6) Desirability of decreasing the number of items appearing in the
B.P., and to include only those drugs which are in general use. Why, for
instance, is serpentinae rhizoma included? Whitla says of this root, "It
is to be regretted that this comparatively worthless drug is still retained
in the B.P." 1

(7) Irregularity of intervals between publication.

(8) The undefined legal status of the B.P.

(9) Insufficient regard for the pharmaceutical needs of the Empire,
especially having regard to the medicinal plants peculiar to certain
localities.

These criticisms would appear to be reasonable. The number and
variety of drugs and preparations which are advertised in various medical
journals of repute, with the placard that they are "less irritating," or
"more soothing," or "less toxic" than the official preparations is
appalling. If the recommendations of the Committee are carried out,
there will be a decided loss in advertisement receipts, but a considerable
gain in the efficiency of official drugs and preparations.

If the Government would only consider the advisability of providing a
fully equipped and special centre for the purpose of analysing drugs supplied
to the services and to the public, it would not be money wasted. A medical
officer once said to the writer, "What is the good of prescribing tincture
digitalis when I haven't the remotest idea when it was manufactured, and
therefore have no indication of its alkaloidal strength?"

SUMMARY OF RECOMMENDATIONS.

The Committee, having sifted all the evidence, drew up certain recom-
mendations which should be carried out in future B.P.'s, and these can be
summarized as follows:—

(1) That it is not necessary to make any alterations in the existing law
relating to the preparation or publication of the B.P.

(2) That the General Medical Council set up forthwith a Selection
Committee for the purpose of nominating a new body to be known as the
Pharmacopoeial Commission. The Selection Committee to consist of four
members nominated by the General Medical Council, three nominated by
the Pharmaceutical Societies of Great Britain, Ireland, and Northern
Ireland respectively, and two nominated by the Medical Research Council.

(3) The Pharmacopoeial Commission to consist of selected authorities
in various departments, but that its numbers should not be restricted, and
that from time to time permanent or temporary members should be

appointed as circumstances arise, including representatives of India and of the Dominions.

(4) That the Commission should be a permanent body, with an office and secretariat.

(5) That the completed volume should be submitted to the General Medical Council for approval before publication.

(6) That in future the B.P. should:
   (a) Be revised and re-issued at stated intervals of ten years, supplements being issued as required.
   (b) Contain only standard drugs in general use throughout the Empire.

(7) That where it is desired in any part of the Empire to sanction the use of particular local drugs, or alternative preparations, not included in the B.P., this should be effected by the Governments concerned by the issue of local supplements or addenda.

(8) That the Governments of the Dominions and India should be asked to set up their own committees to assist and co-operate with the Pharmacopoeia Commission.

(9) That until the financial results of the next edition are seen, the funds necessary for carrying on the work of the Pharmacopoeial Commission be provided by the General Medical Council.

These recommendations, which will no doubt receive Government sanction, will undoubtedly improve the Pharmacopoeia, which, as it now stands, does contain many drugs and preparations which have not stood the test of experience.